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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/477,977	01/05/2000	JOHN H. BURTON	825.001US2	1025

7590

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EXAMINER

ROLLINS, ROSILAND STACIE

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 04/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/477,977	Applicant(s) BURTON ET AL.	
	Examiner Rosiland S. Rollins	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/19/06.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-12 is/are allowed.
- 6) ☒ Claim(s) 13-24, 26-37, 39 and 40 is/are rejected.
- 7) ☒ Claim(s) 25 and 38 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/19/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 13-17, 19-24, 27-32, 34-37, 39 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Haber. Haber discloses a method for variable restricting a body lumen. Figures 5-9 illustrate the steps of guiding an elongate implantable device (1) into the body tissue, the elongate implantable device having an expandable element (2) and a port portion (the rearward end of the proximal tubing 22) , providing a flowable material from a source into the port portion in fluid communication with the expandable element, and at a location separate from the expandable element (col. 5 lines 38-51 & Figure 9) and guiding the device over an elongate probe member (4). **In regards to claims 15 & 16** see column 5 lines 38-41. **Regarding claims 22 and 37** Haber discloses the use of a radio opaque isotonic solution to fill the expandable member (column 5 lines 40-45). During fluoroscopy a radio opaque solution is used to locate the device that is to be visualized. Therefore, it is inherent in Haber's disclosure of the use of a radio opaque solution during implantation of the device that fluoroscopy is utilized.

Claim Rejections - 35 USC, 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 18 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haber and further in view of Andino et al. Haber teaches all of the method steps except placing the implant along two opposite sides of the urethra. Andino et al. teach that it is well known in the art to position periurethral tissue implants along two opposite sides of the urethra to enhance the passive occlusive pressure of the urethral sphincter and thereby achieve continence. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to position the implant of Haber along two opposite sides of the urethra to enhance the effectiveness of the device and increase the passive occlusive pressure of the urethral sphincter.

5. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haber as applied to claim 13 above, and further in view of Whitehouse et al. Haber teaches all of the limitations of the claims except a septum being contained the port portion. Whitehouse et al. disclose that is well known in the art to use a septum to provide a self-sealing seal between a needle and catheter. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a septum in the cavity of the catheter to provide a self-sealing seal between the needle and the catheter so that the inflation medium does not leak out once the needle is removed.

Allowable Subject Matter

Claims 1-12 are allowed.

Claims 25 and 38 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed 1/19/06 have been fully considered but they are not persuasive. Applicant argues that Haber does not show what was asserted, and indeed, shows providing a flowable material directly to the expandable element. Applicant states that this is evidenced by the cannula of Haber delivering fluid directly to the balloon. Applicant also mentions that the Board of Patent Appeals and Interferences did not controvert the evidence presented. In response, Examiner would

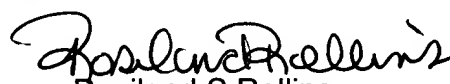
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like to emphasize page 7 of the Decision on Appeal where Judge Frankfort and Judge Bahr found appellants argument with regard to claims 13 and 28 unpersuasive. The judges also went on to affirm the rejection over Haber.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosiland S. Rollins whose telephone number is (571) 272-4772. The examiner can normally be reached on Mon.-Fri. 9:00 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Rosiland S Rollins
Primary Examiner
Art Unit 3739